

FORM PTO-1449
(Rev. 2-32)

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No.

02-1076-A

Serial No.

10/767,516



**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use several sheets if necessary)

Applicant:

Avella, et al

Filing Date:

January 29, 2004

Group:

1654

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
AM	5,438,041	08/21/95	Zheng, et al			
	5,217,648	06/08/93	Beissinger, et al			
	5,194,590	03/16/93	Sehgal, et al			
	5,061,688	10/29/91	Beissinger, et al			
	5,691,453	11/25/97	Wirtz, et al			
	5,084,558	01/28/92	Rausch, et al			
	5,890,852	11/28/98	Rausch, et al			
	5,955,581	09/21/98	Rausch, et al			
	5,691,452	11/25/97	Gawryl, et al			
	6,150,507	11/21/00	Houtchens, et al			
	5,895,810	04/20/99	Light, et al			
	6,271,351	08/07/01	Gawryl, et al			
	6,288,027	09/11/01	Gawryl, et al			
	4,826,811	05/23/89	Sehgal, et al			
↓	5,464,814	11/07/95	Sehgal, et al			
AM	6,498,141	12/24/02	DeWoskin, et al			

EXAMINER

/Abdel Mohamed/

DATE CONSIDERED

06/11/2006

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	Applicant: Avella, et al	
	Filing Date: January 29, 2004	Group: 1654

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
AM	6,323,320	11/27/01	Sehgal, et al			
↓	6,552,173	04/22/03	Sehgal, et al			
↓	5,747,649	05/05/98	Sehgal, et al			
↓	6,133,425	10/17/00	Sehgal, et al			
↓	4,001,401	01/04/97	Sehgal, et al			
↓	4,861,867	08/29/89	Estep, Timothy N.			
↓	6,288,027	09/11/01	Gawryl et al.			
↓	5,206,075	04/27/93	Hodgson Jr.			
↓	5,929,031	07/27/99	Kerwin, et al.			
↓	5,278,272	01/11/94	Lai, et al.			
↓	5,272,236	12/21/93	Lai, et al.			
AM	5,241,031	08/31/93	Mehta, Aspy K.			

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
---------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	Applicant: Avella, et al	
	Filing Date: January 29, 2004	Group: 1654

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
AM	5,695,840	12/9/97	Mueller, Walter B.			
	6,027,776	02/22/00	Mueller, Walter B.			
	5,296,465	03/22/94	Rausch, et al.			
	6,076,457	06/20/00	Vallot, Bernard			
	5,988,422	11/23/99	Vallot, Bernard			
	5,998,361	12/07/99	Bucci, et al			
	5,789,376	08/04/98	Hsia			
	5,380,824	01/10/95	Marschall, et al			
	4,049,673	09/20/97	Scheinberg			
	4,485,174	11/27/84	Chaing, et al			
	4,053,590	10/11/97	Bonsen, et al			
	4,113,853	09/12/78	Funakoshi, et al			
↓	4,650,786	03/18/87	Wong			
AM	4,857,636	08/15/89	Hsia			

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
---------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	Applicant: Avella, et al	
	Filing Date: January 29, 2004	Group: 1654

Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
AM		5,028,588	07/02/1991	Hoffman, et al			
		4,001,200	01/04/1977	Bonsen, et al			
		4,061,736	12/06/1977	Morris, et al			
		4,136,093	01/23/1979	Bonhard, et al			
		4,526,715	07/02/1985	Koke, et al			
		4,529,719	07/16/1985	Tye			
		5,691,453	11/25/1997	Wertz			
		4,711,852	12/08/1987	Jacobson, et al			
✓		4,761,209	08/02/1988	Bonaventure, et al			
AM		4,835,097	05/30/1989	Saunders			

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
--	--

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	Applicant: Avella, et al	
	Filing Date: January 29, 2004	Group: 1654

U.S. PATENT PUBLICATIONS

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
AM	2002/0065211	05/30/02	Jacobs, Jr., et al			

FOREIGN PATENT DOCUMENTS

	Document Number	Date	Country	Class	Subclass	Translation
AM	WO 00/21366	20 April 2000	PCT			YES
AM	WO 97/35883	2 October 1997	PCT			YES
AM	EP 0 361 720 A	4 April 1990	EP			No

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
---------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Applicant: Avella, et al	
		Filing Date: January 29, 2004	Group: 1654

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

AM	Gould, S.A., et al., <i>The Life-Sustaining Capacity of Human Polymerized Hemoglobin when Red Cells Might Be Unavailable</i> , Journal of the American College of Surgeons, 195 (4):445-455 (October, 2002).
	Carson, J.L., et al., <i>Mortality and morbidity in patients with very low postoperative Hb levels who decline blood transfusion</i> , Transfusion, 42: 812-818 (July, 2002).
	Moore, F.A., et al., <i>Trauma Resuscitation</i> , ACS Surgery- Principles & Practice, 31-61 (2002).
	American College of Surgeons Committee on Trauma. <i>Advanced Trauma Life Support Program for Physicians 1997 Instructional Manual</i> , 6 th , ed. Chicago: American College of Surgeons; 98-117 (1997).
	Farion, K.J., et al., <i>Changes in Red Cell Transfusion Practice among Adult Trauma Victims</i> , J. Trauma, 44(4):583-587 (1998).
	Baker, J.B., et al., <i>Type and Crossmatch of the Trauma Patient</i> , J. Trauma, 50(5):878-881(May, 2001).
	DeFoe, G.R., et al., <i>Lowest Hematocrit on Bypass and Adverse Outcomes Associated with Coronary Artery Bypass Grafting</i> , Ann Thorac Surg., 71:769-776 (2001).
	Wu, W.C., et al., <i>Blood Transfusion in Elderly Patients with Acute Myocardial Infarction</i> , New England Journal of Medicine, 345(17):1230-1236 (October, 2001).
	Practice Guidelines for Blood Component Therapy: A report by the American Society of Anesthesiologists Task Force on Blood Component Therapy, Anesthesiology 84(3):732-747 (March, 1996).
	Consensus Conference. <i>Perioperative Red Blood Cell Transfusion</i> , JAMA 260(18): 2700-2703 (November, 1988)
	Gould, S.A., et al., <i>Fluosol DA-20 As A Red Cell Substitute in Acute Anemia</i> , New England Journal of Medicine, 314(26):1653-1656 (June, 1986).
	Spence, R.K., et al., <i>Fluosol DA-20 in the treatment of severe anemia: Randomized, controlled study of 46 patients</i> , Critical Care Medicine, 18(11):1227-1230 (November, 1990).
V	Spence, R.K., et al., <i>Is Hemoglobin Level Alone a Reliable Predictor of Outcome in the Severely Anemic Patient?</i> The American Surgeon, 58(2):92-95 (1992).
AM	Carson, J.L, et al., <i>Severity of Anaemia and Operative Mortality and Morbidity</i> , Lancet 1(8588):727-729 (April, 1988).

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
---------------------------------	-----------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32)	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Applicant: Avella, et al	
(Use several sheets if necessary)		Filing Date: January 29, 2004	Group: 1654

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

AM	Carson, J.L., et al., <i>Effect of anaemia and cardiovascular disease on surgical mortality and morbidity</i> , Lancet, 348(9034):1055-1060 (October, 1996).
	Viele, M.K., et al., <i>What can we learn about the need for transfusion from patients who refuse blood? The experience with Jehovah's Witnesses</i> , Transfusion 34(5):396-401 (1994).
	Sehgal L.R., et al., <i>Polymerized pyridoxylated hemoglobin: A red cell substitute with normal oxygen capacity</i> , Surgery 95:433-438 (1984).
	Amberson, W.R., et al., <i>Clinical Experience with Hemoglobin-Saline Solutions</i> , J. Applied Physiology, 1(7):469-489 (January, 1949).
	Brandt, J.L., et al., <i>The Effects of Hemoglobin Solutions on Renal Functions in Man</i> , Blood, 6:1152-1158 (1951).
	Miller, J.H., et al., <i>The Effect of Hemoglobin on Renal Function in The Human</i> , Journal of Clinical Investigation, 30:1033-1040 (July, 1951).
	Savitsky, J.P., et al., <i>A clinical trial of stroma-free hemoglobin</i> , Clinical Pharmacology Journal, 23(1):73-80 (January, 1978).
	Carmichael, F.J., et al., <i>A phase I study of oxidized raffinose cross-linked human hemoglobin</i> , Crit Care Med, 28(7):2283-2292 (2000).
	Kasper, S.M., et al., <i>Effects of a Hemoglobin-Based Oxygen Carrier (HBOC-201) on Hemodynamics and Oxygen Transport in Patients Undergoing Preoperative Hemodilution for Elective Abdominal Aortic Surgery</i> , Anesth Analg, 83:921-927 (1996).
	LaMuraglia, G.M., et al., <i>The reduction of the allogenic transfusion requirement in aortic surgery with a hemoglobin-based solution</i> , J. Vascular Surgery, 31(2):299-308 (February, 2000).
	Sloan, E.P., et al., <i>Diaspirin Cross-Linked Hemoglobin (DCLHb) in the Treatment of Severe Traumatic Hemorrhagic Shock</i> , JAMA 282:1857-1864 (November, 1999).
	Gould, S.A., et al., <i>Clinical Utility of Human Polymerized Hemoglobin as a Blood Substitute after Acute Trauma and Urgent Surgery</i> , J. Trauma 43(2):325-332 (August, 1997).
V	Gould, S.A., et al., <i>The First Randomized Trial of Human Polymerized Hemoglobin as a Blood Substitute in Acute Trauma and Emergent Surgery</i> , J Am Coll Surg 187(2):113-122 (August, 1998).
AM	Vengelen-Tyler, V., American Association of Blood Banks Technical Manual. 13 th ed., Bethesda (MD): American Association of Blood Banks, p. 389-396 (1999).

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
------------------------------------	--------------------------------------

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.

FORM PTO-1449 (Rev. 2-32) U.S. Department of Commerce Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Atty. Docket No. 02-1076-A	Serial No. 10/767,516
	Applicant: Avella, et al	
	Filing Date: January 29, 2004	Group: 1654

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc).

AM		Huston, P., et al., <i>Withholding Proven Treatment in Clinical Research</i> , New England Journal of Medicine 345(12):912-914 (September, 2001).
		Emanuel, E.J., et al., <i>The Ethics of Placebo-Controlled Trials- A Middle Ground</i> , New England Journal of Medicine, 345(12):915-914 (September, 2001).
		Carson, J.L., et al., <i>Mortality and morbidity in patients with very low blood counts who decline blood transfusion</i> , Transfusion, 42:812-818 (July, 2002).
		Reiner, A.P., <i>Massive Transfusion</i> , Perioperative Transfusion Medicine, p.351-364 (1998).
		Weiskopf, R.B., et al., <i>Human Cardiovascular and Metabolic Response to Acute, Severe Isovolemic anemia</i> , JAMA 279(3): 217-221 (January, 1998).
		Wilkerson, D.K., et al., <i>Limits of cardiac compensation in anemic baboons</i> , Surgery, 103(6):665-670 (1988).
		Levy, P.S., et al., <i>Oxygen Extraction Ratio: A Valid Indicator of Transfusion Need in a Limited Coronary Vascular Reserve?</i> J. Trauma 32(6):769-774 (June, 1992).
		Schwartz, J.P., et al., <i>The Influence of Coronary Stenosis On Transfusion Need.</i> , Cardiothoracic Surgery, Surgical Forum XLIV:226-228 (1993).
		Moss, G.S., et al., <i>Transport of Oxygen and Carbon Dioxide by Hemoglobin-Saline Solution in the Red Cell-Free Primate</i> , Surg. Gynecol Obstet, 142:357-362 (March, 1976).
		Frantantoni, J.C., <i>Points to consider on efficiency evaluation of hemoglobin and perfluorocarbon based oxygen carriers</i> , Transfusion 34(8):712-713 (1994).
		Frantantoni, J.C., <i>Red Cell Substitutes: Evolution of Approaches for Demonstrating Efficacy</i> , Blood-substitutes - Present and Future Perspectives, Elsevier Science S.A., p. 33-39 (1998).
		Sehgal, L.R. et al., <i>Preparation and in vitro characteristics of polymerized pyridoxylated hemoglobin</i> , Transfusion, 23(2):158-162 (1983).
		Sharma, A., et al., <i>An Isologous Porcine Promoter Permits High level Expression of Human Hemoglobin in Transgenic Swine</i> , Biotechnology, 12:55-59 (1994).
AM		Looker, D., et al., <i>A human recombinant haemoglobin designed for use as a blood substitute</i> , Nature, 356:258-260 (1992).

EXAMINER /Abdel Mohamed/	DATE CONSIDERED 06/11/2006
--	--

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication.